

FILING BY "EXPRESS MAIL" UNDER 37 CFR 1.10

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U. S. Department of Commerce Patent and Trademark Office

ATTORNEY'S DOCKET NUMBER

BP/G-32574A

**TRANSMITTAL LETTER TO THE UNITED STATES  
DESIGNATED/ELECTED OFFICE (DO/EO/US)  
CONCERNING A FILING UNDER 35 U.S.C. 371**U.S. APPLICATION NO. (If known, see 37 CFR 1.5)  
10/520,569INTERNATIONAL APPLICATION NO.  
PCT/EP03/07347INTERNATIONAL FILING DATE  
8 July 2003 (08.07.03)PRIORITY DATE CLAIMED  
9 July 2002 (09.07.02)

## TITLE OF INVENTION

LIQUID FORMULATIONS WITH HIGH CONCENTRATION OF HUMAN GROWTH HORMONE (HGH) COMPRISING PHENOL

APPLICANT(S) FOR DO/EO/US

BETZ ET AL.

Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information:

1. ☐ This is a **FIRST** submission of items concerning a filing under 35 U.S.C. 371.
2. ☒ This is a **SECOND** or **SUBSEQUENT** submission of items concerning a filing under 35 U.S.C. 371.
3. ☐ This express request to begin national examination procedures (35 U.S.C. 371(f)) at any time rather than delay examination until the expiration of the applicable time limit set in 35 U.S.C. 371(b) and PCT Articles 22 and 39(1).
4. ☐ A proper Demand for International Preliminary Examination was made by the 19th month from the earliest claimed priority date.
5. ☐ A copy of the International Application as filed (35 U.S.C. 371(c)(2))
  - a. ☐ is transmitted herewith (required only if not transmitted by the International Bureau).
  - b. ☐ has been transmitted by the International Bureau. (See Form PCT/IB/308)
  - c. ☐ is not required, as the application was filed in the United States Receiving Office (RO/US).
6. ☐ A translation of the International Application into English (35 U.S.C. 371(c)(2)).
7. ☐ Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. 371(c)(3)).
  - a. ☐ are transmitted herewith (required only if not transmitted by the International Bureau).
  - b. ☐ have been transmitted by the International Bureau.
  - c. ☐ have not been made; however, the time limit for making such amendments has NOT expired.
  - d. ☐ have not been made and will not be made.
8. ☐ A translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371(c)(3)).
9. ☒ An executed Declaration and Power of Attorney (original or copy) (35 U.S.C. 371(c)(4)).
10. ☐ A translation of the annexes to the International Preliminary Examination Report under PCT Article 36 (35 U.S.C. 371(c)(5)).

**Items 11. to 16. below concern document(s) or information included.**

11. ☐ An Information Disclosure Statement under 37 CFR 1.97 and 1.98.
12. ☐ An assignment document for recording. A separate cover sheet in compliance with 37 CFR 1.28 and 1.31 is included.
13. ☐ A FIRST preliminary amendment.  
☐ A SECOND or SUBSEQUENT preliminary amendment.
14. ☐ An Application Data Sheet under 37 CFR 1.76.
15. ☐ A substitute specification.
16. ☐ A change of power of attorney and/or address letter.
17. ☐ A computer-readable form of the sequence listing in accordance with PCT Rule 13ter(2) and 37 CFR 1.82, 1.85, 1.86, 1.87, 1.88, 1.89, 1.90, 1.91, 1.92, 1.93, 1.94, 1.95, 1.96, 1.97, 1.98, 1.99, 2.00, 2.01, 2.02, 2.03, 2.04, 2.05, 2.06, 2.07, 2.08, 2.09, 2.10, 2.11, 2.12, 2.13, 2.14, 2.15, 2.16, 2.17, 2.18, 2.19, 2.20, 2.21, 2.22, 2.23, 2.24, 2.25, 2.26, 2.27, 2.28, 2.29, 2.30, 2.31, 2.32, 2.33, 2.34, 2.35, 2.36, 2.37, 2.38, 2.39, 2.40, 2.41, 2.42, 2.43, 2.44, 2.45, 2.46, 2.47, 2.48, 2.49, 2.50, 2.51, 2.52, 2.53, 2.54, 2.55, 2.56, 2.57, 2.58, 2.59, 2.60, 2.61, 2.62, 2.63, 2.64, 2.65, 2.66, 2.67, 2.68, 2.69, 2.70, 2.71, 2.72, 2.73, 2.74, 2.75, 2.76, 2.77, 2.78, 2.79, 2.80, 2.81, 2.82, 2.83, 2.84, 2.85, 2.86, 2.87, 2.88, 2.89, 2.90, 2.91, 2.92, 2.93, 2.94, 2.95, 2.96, 2.97, 2.98, 2.99, 3.00, 3.01, 3.02, 3.03, 3.04, 3.05, 3.06, 3.07, 3.08, 3.09, 3.10, 3.11, 3.12, 3.13, 3.14, 3.15, 3.16, 3.17, 3.18, 3.19, 3.20, 3.21, 3.22, 3.23, 3.24, 3.25, 3.26, 3.27, 3.28, 3.29, 3.30, 3.31, 3.32, 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U.S. APPLICATION NO. (if known, see 37 CFR 1.5)  
10/520,569

INTERNATIONAL APPLICATION NO.  
PCT/EP03/07347

ATTORNEY'S DOCKET NUMBER  
BK 2574A

The following fees are submitted:

21. Basic national fee. . . . . \$

22. Examination Fee  
If International preliminary examination report was prepared by USPTO  
and all claims satisfy provisions of PCT Article 33(1)-(4) . . . . . \$  
  
All other situations. . . . . \$

23. Search fee  
If Search fee (37 CFR 1.445(a)(2)) has been paid on the international  
application to the USPTO as an International Searching Authority. . . . . \$  
If International Search Report was prepared and provided to the Office. . . \$  
All other situations. . . . . \$

**CALCULATIONS** PTO USE  
ONLY

**TOTAL OF 21, 22 AND 23 =**

\$ 0

Additional fee for specification and drawings filed in paper over 100 sheets (excluding sequence listing or computer program listing filed in an electronic medium). The fee is \$250 for each additional 50 sheets of paper or fraction thereof.

Total Sheets	Extra sheets	Number of each additional 50 or fraction thereof (round up to a whole number)	RATE
- 100 =	/50 =	X	\$ 250

Surcharge of \$130 for furnishing the oath of declaration later than ☒ 30 months from the earliest claimed priority date (37 CFR 1.492(e)). \$ 130

CLAIMS	NUMBER FILED	NUMBER EXTRA	RATE
Total claims	- 20 =	X	\$ 50
Independent claims	- 3 =	X	\$ 200
MULTIPLE DEPENDENT CLAIM(S) (if applicable)			+ \$ 360

**TOTAL OF ABOVE CALCULATIONS =** \$ 130

Reduction of 1/2 for filing by small entity, if applicable. Verified Small Entity Statement must also be filed (Note 37 CFR 1.9, 1.27, 1.28).

**SUBTOTAL =** \$ 130

Processing fee of \$130 for furnishing the English translation later than ☐ 30 months from the earliest claimed priority date (37 CFR 1.492(f)). + \$

**TOTAL NATIONAL FEE =** \$ 130

Fee for recording the enclosed assignment (37 CFR 1.21(h)). The assignment must be accompanied by an appropriate cover sheet (37 CFR 3.28, 3.31). \$40 per property + \$

**TOTAL FEES ENCLOSED =** \$ 130

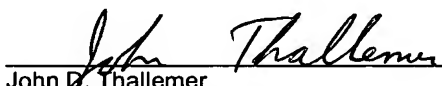
Amount to be: refunded	\$
charged	\$

- a. ☐ A check in the amount of \$\_\_\_\_\_ to cover the above fees is enclosed.
- b. ☒ Please charge Deposit Account No. 19-0134 in the name of Novartis in the amount of \$130 to cover the above fees. A duplicate copy of this form is enclosed.
- c. ☒ The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. 19-0134 in the name of Novartis.

**NOTE: Where an appropriate time limit under 37 CFR 1.494 or 1.495 has not been met, a petition to revive (37 CFR 1.137(a) or (b)) must be filed and granted to restore the application to pending status.**

Send all correspondence to the address associated with Customer No. 001095, which is currently:

Novartis  
Corporate Intellectual Property  
One Health Plaza, Building 104  
East Hanover, NJ 07936-1080

  
John D. Thallemer  
Attorney for Applicants  
Reg. No. 34,940  
(862) 778-7945



## UNITED STATES PATENT AND TRADEMARK OFFICE

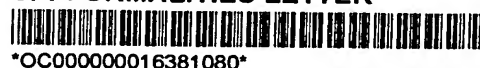
UNITED STATES DEPARTMENT OF COMMERCE  
 United States Patent and Trademark Office  
 Address: COMMISSIONER FOR PATENTS  
 P.O. Box 1450  
 Alexandria, Virginia 22313-1450  
 www.uspto.gov

U.S. APPLICATION NUMBER NO.	FIRST NAMED APPLICANT	ATTY. DOCKET NO.
10/520,569	Michael BETZ	BP/G-32574A/BCK

1095  
 NOVARTIS  
 CORPORATE INTELLECTUAL PROPERTY  
 ONE HEALTH PLAZA 104/3  
 EAST HANOVER, NJ 07936-1080

INTERNATIONAL APPLICATION NO.	
PCT/EP03/07347	
IA. FILING DATE	PRIORITY DATE
07/08/2003	07/09/2002

CONFIRMATION NO. 5279  
 371 FORMALITIES LETTER



\*OC000000016381080\*

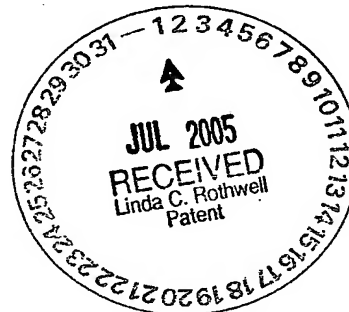
JDT

Date Mailed: 06/29/2005

### NOTIFICATION OF MISSING REQUIREMENTS UNDER 35 U.S.C. 371 IN THE UNITED STATES DESIGNATED/ELECTED OFFICE (DO/EO/US)

The following items have been submitted by the applicant or the IB to the United States Patent and Trademark Office as a Designated / Elected Office (37 CFR 1.495).

- Copy of the International Application filed on 01/07/2005
- Copy of the International Search Report filed on 01/07/2005
- Copy of IPE Report filed on 01/07/2005
- Preliminary Amendments filed on 01/07/2005
- Information Disclosure Statements filed on 01/07/2005
- U.S. Basic National Fees filed on 01/07/2005
- Priority Documents filed on 01/07/2005



The following items **MUST** be furnished within the period set forth below in order to complete the requirements for acceptance under 35 U.S.C. 371:

- Oath or declaration of the inventors, in compliance with 37 CFR 1.497(a) and (b), identifying the application by the International application number and international filing date.
- \$130 Surcharge for providing the oath or declaration later than 30 months from the priority date (37 CFR 1.492(e)) is required.

#### SUMMARY OF FEES DUE:

Total additional fees required for this application is \$130 for a Large Entity:

- \$130 Late oath or declaration Surcharge.

ALL OF THE ITEMS SET FORTH ABOVE MUST BE SUBMITTED WITHIN TWO (2) MONTHS FROM THE DATE OF THIS NOTICE OR BY 32 MONTHS FROM THE PRIORITY DATE FOR THE APPLICATION, WHICHEVER IS LATER. FAILURE TO PROPERLY RESPOND WILL RESULT IN ABANDONMENT.

DOCKETED FOR: Aug. 29, 2005

The time period set above may be extended by filing a petition and fee for extension of time under the provisions of 37 CFR 1.136(a).

Applicant is reminded that any communications to the United States Patent and Trademark Office must be mailed to the address given in the heading and include the U.S. application no. shown above (37 CFR 1.5)

*A copy of this notice **MUST** be returned with the response.*

FRANCINE YOUNG

Telephone: (703) 308-9140 EXT 215

**PART 1 - ATTORNEY/APPLICANT COPY**

U.S. APPLICATION NUMBER NO.	INTERNATIONAL APPLICATION NO.	ATTY. DOCKET NO.
10/520,569	PCT/EP03/07347	BP/G-32574A/BCK

FORM PCT/DO/EO/905 (371 Formalities Notice)